



NOVABAY PHARMACEUTICALS (AMEX: NBY)

- **Impetigo Phase II clinical trial yields favorable top-line data – complete results to be reported in the fall.**
- **The next study will optimize the dosing regimen in preparation for a pivotal study in 2012.**
- **Recent results make an opt-in decision easy for Galderma, in our view.**
- **We reiterate our BUY recommendation and our target price of \$9.00 per share.**

NovaBay Pharmaceuticals (AMEX: NBY) has developed a platform of antimicrobial compounds, called Aganocides®, that destroy microbes without permitting the development of resistance. These compounds are derivatives of naturally occurring chemicals used by the innate immune system to fend off bacteria, viruses, and fungi. The Company has entered into partnerships with two major corporations in dermatology and ophthalmology to commercialize its Aganocides, Galderma and Alcon.

The newly released data from a Phase IIa clinical trial provide strong evidence of efficacy against a skin infection, impetigo, which strikes many children and some adults. The primary infectious agents behind this condition are *Staphylococcus aureus* and streptococci. The dose-escalation study found that NovaBay's NVC-422 resulted in clinical cure rates in the range of 85%-95%, depending on the dose, well above the historical placebo response rates of 30%-50%. Moreover, the cure rate against MRSA was 100%. The drug exhibited a good safety profile with only minor redness and itching reported, and no patients dropped out of the study. The complete results will be presented at a scientific meeting later this year. Given the trial's success, we look for Galderma to pay a

Share Price (7/21/10)	\$2.09
52-Week Price Low / High	\$1.62-\$2.71
Mkt. Capitalization (issued)	\$48.7 million
Shares Outstanding (issued)	23.31 million
12-month Target Price	\$9.00
Website	www.novabaypharma.com



milestone of approximately \$5 million by March 2011 in accordance with the licensing agreement.

NovaBay plans to initiate a Phase IIb study later this year to optimize the dose and dosing regimen in preparation for a pivotal trial. Hence, the impetigo program is on schedule for a possible commercial launch in 2014.

We believe NovaBay shares are undervalued relative to a peer group, and we are maintaining our BUY rating and share price target of \$9.00.

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EXCELLENT TOP-LINE RESULTS FROM THE IMPETIGO PHASE II TRIAL

NovaBay initiated a dose-escalation study of its lead compound NVC-422 for the treatment of a skin infection, impetigo, in September 2009. (For a discussion of impetigo, see the blue area below.) The study yielded solid proof-of-concept data in support of further investigations into the Aganocide for this skin infection.

Impetigo is a skin infection that is caused largely by two bacteria, *Staphylococcus aureus* and group A streptococci. (See Figure 1.) Prevalence varies significantly by age, geography, and living conditions. Children are most affected, as one study in England found that impetigo accounts for about 56% of all skin infections in children, 16% in adults, and 6% in the elderly.¹ Geographically, the highest reported incidence rates are found in tropical regions with relatively poor living conditions (e.g., Fiji where the average income is about \$6,000 per annum and 25.6% of children between 5 and 15 years of age are infected), while the lowest rates have been reported in temperate climates and countries with higher standards of living.^{2,3} These epidemiological findings reflect differences in sanitary conditions, exposure to environmental factors that facilitate skin infections (e.g., mosquito bites), and the proportion of body surface protected by clothing from dermatological insults. Over the past three decades, impetigo has become increasingly prevalent in more developed countries, due partly to growing reliance on day-care centers for child care. Then, too, drug resistant strains of bacteria have caused the number of impetigo-related hospital admissions to more than double in the United States between 1999 and 2005.⁴



Source: www.skininfections.com

Figure 1. Common appearance of impetigo. Infections often occur near the mouth and nose, but may spread to other parts of the body due to the infectious nature of the microbes. Red sores that rupture quickly, ooze for a period, and then form a hard crust are the most common type of impetigo. The most serious form, which is usually on the legs or feet, involves penetration of the dermis and formation of deep ulcers.



Source: www.webmd.com

Small lesions are usually treated with mupirocin ointment (generic and sold by GlaxoSmithKline as Bactroban[®]), though systemic antibiotic therapy is required for bulbous impetigo, which is treated with systemic antibiotics. An important concern is the development of resistance to mupirocin and to such systemic antibiotics as aminoglycosides (e.g., gentamicin), beta-lactams (e.g. penicillins and cephalosporins), and macrolides (e.g., erythromycin). Impetigo that is left untreated or is treated improperly can lead to much more serious conditions, including cellulitis, abscess, bacteremia, sepsis, and post-streptococcal glomerulonephritis. Hence, a new antimicrobial agent that is capable of combating antibiotic-resistant bacteria, particularly if it does not release enterotoxin from Staph infections would likely be well received. The broad-spectrum antimicrobial agent NVC-422 fits the bill.

¹ Elliot, AJ, et al. The association between impetigo, insect bites and air temperature: a retrospective 5-year study (1999-2003) using morbidity data collected from a sentinel general practice network database. *Fam Pract* 2006; 23(5): 490.

² Elliot, AJ, et al. The association between impetigo, insect bites and air temperature: a retrospective 5-year study (1999-2003) using morbidity data collected from a sentinel general practice network database. *Fam Pract* 2006; 23(5): 490.

³ Fleming, DM, et al. Recent changes in the prevalence of diseases presenting for health care. *Br J Gen Pract* 2005; 55: 589.

⁴ Jung, MA, et al. Enhanced detection of *Staphylococcus aureus*-related hospitalizations using administrative databases, United States-1999-2005. Presented at the 18th annual scientific meeting of the Society for Healthcare Epidemiology of America, April 6, 2008.

THE STUDY DESIGN

The Phase IIa study enrolled 129 patients who presented with impetigo to two treatment centers in the Dominican Republic. Bacteriological samples taken upon entry into the trial determined that 90% of the patients had infections involving a single organism (80% *Staphylococcus aureus* and 20% streptococci) and 10% had infections with multiple infectious agents. Methicillin-resistant *Staphylococcus aureus* (MRSA) was identified in 8% of the patient population. Patients were treated by the enrolling physician at the time of entry and subsequently by their parents who were required to keep a diary of the applications and any observations of toxicity and efficacy. The protocol called for 3 applications of NVC-422 gel per day for seven days, though only 14 of the prescribed 21 applications were required to be considered in compliance. Patients visited the treatment centers on days 4, 8, and 15. The day-4 visit was intended to ensure the parents were using the drug properly and that the parents were recording their observations. On day 8, the patients were evaluated for clinical and bacteriological responses, and the day-15 visit was used to determine if there were any relapses.

THE RESULTS

Of the 129 patients enrolled, 117 were eligible for evaluation, as not all patients complied with the study's treatment protocol. (The actual range of prescribed doses administered was 80%-95%.) Still, the preliminary results were better than expected, as all three concentrations of NVC-422 were associated with significant response rates. (See Table 1 for the Skin Infection Rating Scale.) NovaBay has not disclosed the actual concentrations tested, other than to designate them as "low, medium, and high." But even the lowest dose was able to achieve meaningful results, as the clinical response rates to the low, medium, and high doses were 85%, 87%, and 92% respectively, while the bacteriological response rates were 87%, 89%, and 95%. In addition, 100% of the patients with MRSA infections responded to the therapy. And at day 15, no patients who had responded by day 8 had impetigo.

Table 1. Skin Infection Rating Scale

Sign/symptom	Score	Definition
Blistering	0=Absent	No evidence of blisters
	1=Mild	Few raised vesicles present on close evaluation
	2=Moderate	Fluid filled vesicles are obvious and are bothersome to the patient
	3=Severe	Extensive area covered with many vesicles which may include large bullous vesicles
Exudate/pus	0=Absent	No evidence of exudate or pus
	1=Mild	Small amounts of fluid/pus coming from the lesions
	2=Moderate	Exudate/pus infected area is moderate
	3=Severe	Extensive areas infected and there is draining exudate
Crusting	0=Absent	No evidence of crusting
	1=Mild	A few areas have some evidence of crusting lesions
	2=Moderate	Crusting is present throughout the infected area
	3=Severe	Thick crusting appears over the entire impetiginous area
Erythema/inflammation	0=Absent	Skin tone and color are normal; no signs of erythema or inflammation
	1=Mild	Skin is pink with minimal signs of inflammation
	2=Moderate	Skin is red with definite signs of inflammation
	3=Severe	Skin is red and severe inflammation is present
Itching/pain	0=Absent	No signs of itching or indication of pain
	1=Mild	Some evidence of scratching or rubbing the area is evident and patient reports minor discomfort
	2=Moderate	Evidence of scratching and patient reports bothersome, painful lesions
	3=Severe	Evidence of extensive scratching and patient reports pain that interferes with daily activities or sleep.

Source: FDA Draft Guidance on Mupirocin, June 2010.

The results compare well with those reported for the two topical antibiotics that are in use today. The clinical trial of mupirocin (sold as a generic drug and by GlaxoSmithKline as Bactroban[®]) reported a success rate of 71%, while retapamulin (sold by GlaxoSmithKline as Altabax[®]) had a response rate of 85% in its clinical trial. However, Altabax is approved only for impetigo involving methicillin sensitive strains of *Staphylococcus aureus*, it is not approved for MRSA.⁵ And mupirocin, which was originally a good antibiotic, has lost some potency as resistant strains of bacteria have developed since its approval in 1995.

NVC-422 exhibited a good safety profile in the Phase IIa study. Patients reported low or moderate levels of redness and/or itching associated with the drug, and none left the study over these issues. (Note that the symptoms of impetigo include both erythema and itching.) Moreover, the clear gel formulation was easy to apply, which is an important consideration, given the crusting that occurs on the wound.

THE NEXT CLINICAL TRIAL

NovaBay is preparing to speak with the FDA regarding the next clinical trial that it would like to conduct. The Phase IIb study will expand the dose-response curve, largely to lower doses to better establish the concentration range over which NVC-422 is clinically effective. Another goal is to test different dosing regimens that we believe will include a twice-daily application. Since the side effect profile in the Phase IIa study was very favorable at efficacious doses, safety probably will not be the focus of the next trial, though that type of information will undoubtedly be recorded. The Phase IIb study, which should commence in the fourth quarter, will enroll 120 – 150 patients in the Dominican Republic and the United States. The goal is to identify the drug formulation and dosing regimen that will be used in a pivotal study that is tentatively scheduled to begin in 2012.

LARGE COMMERCIAL OPPORTUNITIES

NovaBay hired outside consultants to conduct a physician survey focused on impetigo. In all, 120 doctors, including primary care physicians and dermatologists in the United States, participated. The current therapeutic choices were mupirocin (60%) and Altabax (30%). In addition, 80% believe that the incidence of MRSA infections is going to rise over the next five years and that resistance to mupirocin will rise as well. These answers indicate that there is ample room in the marketplace for an improved therapy for impetigo. When the same physicians were provided with information about NVC-422, 85% believed that they would use it therapeutically or prophylactically for other indications.

The results of the survey have reinforced NovaBay's clinical development strategy for its gel formulation of NVC-422. The Company intends to speak with the FDA about testing the drug against other uncomplicated skin infections that may accompany burns, atopic dermatitis, surgical incisions, and biopsies. Any one of these would greatly expand the market. But how much of an effect any one would have is difficult to predict. Indeed, simply estimating the size of the impetigo market poses a challenge, since infections vary by geographic location and season, and hard epidemiological data is not available for many countries. However, prescription data from major drug markets does underscore the prevalence of skin infections. In 2009, 1.4 million prescriptions were written in the United States for impetigo and 2.3 million were written in Europe. Overall, uncomplicated skin infections account for more than 200 million doctor visits annually in the United States, with treatment costs of more than \$350 million.

⁵ FDA Warning Letter to GlaxoSmithKline regarding NDA 22-055, April 19, 2010.

A SIZABLE MILESTONE PAYMENT EXPECTED

NovaBay conducted the Phase IIa clinical trial under its agreement with Galderma. Now, the dermatology drug specialist has the option to continue its involvement in the program. Based on the favorable safety and efficacy data released recently, we believe Galderma will continue the collaboration and pay NovaBay a milestone of roughly \$5 million within the next 8 months. That money should more than support the Phase IIb trial. In the unlikely event that Galderma opts out, NovaBay has other potential partners that have expressed an interest in NVC-422 for dermatological indications.

INVESTMENT CONSIDERATIONS

NovaBay is well along in developing its gel formulation of NVC-422 as a first-line therapy for a wide range of dermatological infections via a collaboration with Galderma, and it is making progress with another partner, Alcon, for ophthalmological indications. These are huge markets that are not well served by antibiotics, since the infectious agents are not always readily identifiable or treatable with an antibiotic and many bacteria are developing resistance to today's drugs. Moreover, NovaBay is investigating an Aganocide formulation for catheter-associated urinary tract infections, which constitute a \$250 million market. And as shown below, these programs are expected to yield ample milestones that investors may use to monitor the Company's progress in the months ahead:

NEAR-TERM MILESTONES

- Q3'10 Report results from proof-of-concept impetigo clinical trial.
- Q4'10 File IND to initiate otitis externa clinical trial with Alcon.
- Q4'10 Report top-line results from viral conjunctivitis Phase II clinical trial sponsored by Alcon.
- Q4'10 Commence Phase IIb impetigo clinical trial with Galderma.
- Q4'10 File IND to initiate sinusitis clinical trial sponsored by Alcon.
- Q4'10 Report results from Phase IIa catheter-associated urinary tract infection clinical trial.
- H1'10 Initiate Phase IIa catheter-associated urinary tract infection trial.
- H1'11 Initiate Phase III viral conjunctivitis trial with Alcon.
- H2'10 Initiate Phase IIb catheter-associated urinary tract infection clinical trial.
- H1'11 Commence Phase III catheter-associated urinary tract infection clinical trial.
- H1'121 Initiate Phase III impetigo clinical trial with Galderma.

COMPARATIVE VALUATION ANALYSIS

We assembled a peer group of companies by limiting our search to those with market capitalizations below \$200 million and with less than \$40 million of revenue in 2009. Other criteria included a relatively small number of drugs under development with the lead candidate in a clinical trial.

Table 2. Market Capitalizations of NovaBay's Peer Group

Company	Ticker	Therapeutic Area	Most Adv Phase	Market Cap
PolyMedix, Inc.	PYMX.OB	Infectious disease	Phase 1	\$76.1
Provectus Pharmaceuticals	PVCT.OB	Oncology & dermatology	Phase 2	\$78.8
Renovo Group plc	LSE: RNVO	Dermatology	Phase 3	\$71.8
Oncolytics Biotech	ONCY	Oncology	Phase 2	\$168.1
Average Market Capitalization:				\$98.7

The group consists of three companies with drugs applicable to dermatology and/or oncology and one with an anti-infective compound in clinical trials. None of the companies booked significant revenue last year and all were unprofitable. In addition, each appears likely to license their lead candidates to a marketing partner, much as NovaBay has entered into collaborations with Galderma and Alcon.

The average market capitalization of the peer group is \$98.7 million, which is approximately twice the \$48.7 million valuation awarded NovaBay. Even if the pure oncology company Oncolytics Biotech is eliminated from the calculation, the peer group's valuation averages \$76.5 million, or 55% higher than NovaBay's. Hence, we believe NBY shares are significantly undervalued today. And based upon the value-driving milestones that are expected to be achieved in the next 12 to 18 months, we are maintaining our BUY rating on the stock with a price target of \$9.00 per share.

INVESTMENT CONCERNS AND RISKS

For a complete description of risks and uncertainties related to NovaBay Pharmaceuticals business, see NovaBay's 10K reports, which can be accessed from the Company's website, www.novabaypharma.com. Potential risks include:

- **Stock risk and market risk:** There is a limited trading market for the Company's common stock. There can be no assurance that an active and liquid trading market will develop or, if developed, that it will be sustained, which could limit one's ability to buy or sell the Company's common stock at a desired price. Investors should also consider technical risks common to many small-cap or micro-cap stock investments, such as small float, risk of dilution, dependence upon key personnel, and the strength of competitors that may be larger and better capitalized.
- **Competitive risk:** The pharmaceutical market continues to evolve, and research and development are expected to continue. Other companies are already established players in antimicrobial markets and are actively engaged in the development of new drugs that may directly or indirectly compete with those being pursued by NovaBay. These companies may have substantially greater research and development capabilities, as well as significantly greater marketing, financial, and human resources than the Company.
- **Products still in development phases:** NovaBay's products are still at a precommercialization stage. Such products may appear to be promising, but may not reach commercialization for various reasons, including failure to demonstrate safety and efficacy in large clinical trials and/or the inability to be manufactured at a competitive cost. And even if its products are commercialized, there can be no assurance that they will be accepted by physicians, patients, or healthcare payers, which may prevent the Company from becoming profitable.
- **Funding requirements:** It is difficult to predict NovaBay's future capital requirements. The Company may need additional financing to continue funding the development of its products and their production. There is no guarantee that it can secure the desired future capital or, if sufficient capital is secured, that current shareholders will not suffer significant dilution.
- **Regulatory risk:** There is no guarantee that the Company's products will be approved by the U.S. Food and Drug Administration (FDA) or international regulatory bodies for marketing in the U.S. or abroad.
- **Patent risk:** The pharmaceutical industry is one in which patents have not always provided sufficient protection against competition. There can be no assurance that NovaBay's patents will provide sufficient protection to exclude competitors and that patent litigation will not become a financial burden.

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PRICE CHART – 2 Year



4/21/2010 – Initiating Coverage: share price: \$2.50; rating: BUY; 12-month price target: \$9.00; **7/22/2010** – Update Rpoert: share price \$2.09; rating: BUY; 12-month price target: \$9.00.

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